

**REMARKS**Status of the Claims

Claims 23, 24, and 31-47 are currently pending in the present application. Claims 1-22 and 25-30 have been cancelled. New claims 48-50 have been added. New claims 48-50 are drawn to the same invention as claims 23, 24, and 31-47. Claims 23, 24, and 31-50, directed to a method of identifying genes which are modulated by  $\Delta$ FosB, are currently under examination.

Amendments to the Claims

Claims 23 and 45 have been amended to provide separate specific embodiments of the invention. Amendments to claims 23 and 45 do not introduce prohibited new matter. Support for the amendments to claims 23 and 45 can be found throughout the specification, especially in paragraphs [0014], [0016], and [0017].

New claims 48-50 have been added to provide separate specific embodiments of the claimed invention. New claims 48-50 do not introduce prohibited matter. Support for claims 48-50 can be found in paragraph [0018].

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 34, 35, 46, and 47 are rejected as purportedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action alleges that claims 34, 35, 46, and 47 are vague, unclear, and incomplete in how the lysates and extracts are used in the methods set forth in claims 23 and 45. Applicants respectfully point out that cell lysates and nuclear extracts are routinely used for transcription assays. Thus, the use of cell lysates and nuclear extracts to determine which genes are differentially expressed is well known. Changes in the levels of gene expression can be determined by any hybridization assay including microarrays and Northern blot analysis, as well as Western blot analysis, immunoassay, PCR, *etc.* On page 42, the specification specifically details the use of nuclear extract for gene expression.

As pointed out in §2173.02 of the MPEP, the test of indefiniteness is whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). Thus, if one skilled in the art is able to ascertain the meaning of the terms recited in the claims, then the claims are not indefinite. Since lysates and nuclear extracts are routinely used for determining levels of gene expression, those skilled in the art would know how to practice the claimed invention of claims 34, 35, 46, and 47. Thus, the claims are not indefinite.

#### Rejections Under 35 U.S.C. § 102

A. Claims 23, 24, 31, 32, and 36-45 are rejected under 35 U.S.C. § 102(b) as purportedly being anticipated by Nestler *et al.*

Claim 23 and its dependent claims, as they stand, are directed to a method of identifying genes associated with osteogenesis or adipogenesis that are modulated by  $\Delta$ FosB comprising inducing the expression of  $\Delta$ FosB in a cell associated with osteogenesis or adipogenesis and determining which genes associated with adipogenesis or osteogenesis are differentially expressed, thereby identifying genes associated with osteogenesis or adipogenesis that are modulated by  $\Delta$ FosB. Claim 45, as it stands, is directed to a method of identifying genes associated with osteogenesis or adipogenesis that are modulated by  $\Delta$ FosB comprising inducing the expression of  $\Delta$ FosB and determining which genes associated with adipogenesis or osteogenesis are differentially expressed, thereby identifying genes associated with osteogenesis or adipogenesis that are modulated by  $\Delta$ FosB.

Nestler *et al.* do not teach a method of identifying genes associated with osteogenesis or adipogenesis that are modulated by  $\Delta$ FosB comprising inducing  $\Delta$ FosB in cells and determining which genes associated with osteogenesis or adipogenesis are differentially expressed. Nestler *et al.* do not teach that  $\Delta$ FosB modulates osteogenesis or adipogenesis. Further, Nestler *et al.* do not disclose that an increase in the expression of  $\Delta$ FosB is associated with osteogenesis or inhibition of adipogenesis.

The Office Action alleges that Nestler *et al.* teach the use of mice to identify specific  $\Delta$ FosB targets. However, these targets are not associated with osteogenesis or adipogenesis. Rather, these targets are associated with brain function. In the absence of teachings by Nestler *et al.* correlating  $\Delta$ FosB and osteogenesis or adipogenesis, Nestler *et al.* do not anticipate the claimed invention.

#### Rejections Under 35 U.S.C. § 103

Claims 23, 31, 33, 34, 35, 45, 46, and 47 are rejected under 35 U.S.C. 103(a) as purportedly being unpatentable over Nestler *et al.* and Agamemnon *et al.*

As discussed above, the claims as they stand are directed to methods of identifying genes associated with osteogenesis or adipogenesis that are modulated by  $\Delta$ FosB. The deficiencies of Nestler *et al.* have been discussed above. Nestler *et al.* do not teach a method of identifying genes associated with osteogenesis or adipogenesis that are modulated by  $\Delta$ FosB. Likewise, Agamemnon *et al.* does not disclose a method of identifying genes associated with osteogenesis or adipogenesis that are modulated by  $\Delta$ FosB. Neither Nestler *et al.* nor Agamemnon *et al.* teach that  $\Delta$ FosB modulates osteogenesis and adipogenesis. The cited references also do not disclose that an increase in the expression of  $\Delta$ FosB is associated with osteogenesis or inhibition of adipogenesis. Accordingly the combination of the cited references do not render the claimed invention obvious.

The Office Action asserts that Nestler *et al.* teach the generation of transgenic  $\Delta$ FosB mice and the use of said mice in analyzing the affect of  $\Delta$ FosB. However, as discussed above, Nestler *et al.* do not teach that the use of these transgenic mice to identify genes associated with osteogenesis or adipogenesis.

The Office Action also asserts that Agamemnon *et al.* teach a transgenic mouse model where the fosB is provided as a transgene under the control of the LTR promoter, allowing the expression of fosB in a variety of tissues. However, as discussed above, Agamemnon *et al.* do not disclose the use of the transgenic mice to identify genes associated with osteogenesis or adipogenesis.

Accordingly, given the deficiencies of the cited references, there would be no motivation to combined the cited references and even if combined, the teachings of the cited references would not render the claimed invention obvious.

Conclusion

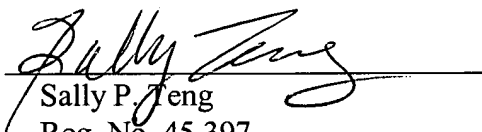
The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments, reconsideration, and the timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, they are invited to telephone the undersigned at their convenience.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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